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| 09/092,296 | 06/05/98 | BILLING-MEDEL | 6104.US.01 |

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HM12/1023

EXAMINER

NICKOL, G

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/092,296

Applicant(s)

BILLING-MEDEL ET AL.

Examiner

Gary B. Nickol Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-10, 13 and 35-45 is/are pending in the application.
- 4a) Of the above claim(s) 7-10 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Response to Amendment

The Amendment filed August 15, 2001 (Paper No. 20) in response to the Office Action of December 27, 2000 is acknowledged and has been entered. Claims 7-10, 13, and 35-45 are pending. Claims 1-6, 11-12, 14, and 16-34 were cancelled. New claims 35-45 were added. Claims 7-10, and 13 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. Claims 35-45 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Specification

The specification remains objected to with regard to the use of trademarks (Paper No. 16, page 2) . The use of trademarks such as REDICOL disclosed on page 61, line 34, of the specification has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Priority

It is maintained that all pending claims of the present application will receive a priority date of June 5, 1998, the effective filing date for the reasons of record in Paper No. 16, page 3. Applicants have not provided evidence to the contrary, and the effective priority date remains at 6-5-98.

REJECTIONS MAINTAINED

Claims 38 and 41 remain rejected under 35 U.S.C. 112, first paragraph for reasons of record in Paper No. 16, page 4 with regard to epitopes. Applicants argue (Paper No. 20, page 8) that new claims 35-45 do not include percent identity language and that the new claims are in condition for allowance. This argument has been considered but it not found persuasive. Applicant has not amended the claims comprising epitope language. Thus, applicants arguments have not been found persuasive, and the rejection is maintained.

Claims 35-45 remain rejected under 35 U.S.C. 101 for the reasons of record in Paper No. 16, pages 6-9.

Applicant's argue (Paper No. 20, page 8) that the Examiner states that the specification teaches general utility for the invention, not a specific utility and that these claims have been cancelled. This argument has been considered but it not found persuasive. Cancellation and or amendment of the claims does not resolve the issues of utility. Also, the previous rejection did not state that a "general utility" of the invention existed. The rejection stated that the claimed

Art Unit: 1642

invention was not supported by a specific asserted or well established utility and that for the reasons set forth, credibility of any utility could not be assessed.

Applicants further argue that the specification teaches that the claimed gene products detected themselves in lung samples but not in non-lung RNA samples, thereby establishing that lung tissue is the host tissue of the claimed gene products. This argument has been considered but it not found persuasive. Evidence that the claimed gene products are exclusively expressed in lung tissues does not alone provide a basis for assessing utility since it is not clear how such differential expression will be applied as a real world utility.

Applicants further argue that the detection of the claimed gene products outside (emphasis added) their host lung tissue, is diagnostically useful because it indicates that the host tissue is in a diseased state. This argument has been considered but it not found persuasive. There is nothing in the specification to indicate that the claimed products are detected outside their host lung tissue. The disclosure only teaches differential expression of mRNA from various tissue extracts (Figure 3). Applicants also argue that the polynucleotides are of interest when they are overexpressed in a tissue or body compartment where their normal occurrence is very low or non-existence wherein such overexpression indicates that a disease has altered the polynucleotides so that they escape from their host tissue (in this case lung tissue) into other areas of the body. This argument has been considered but it not found persuasive for reasons of record. There is no evidence to suggest that the claimed polynucleotides are overexpressed in lung tissues.

The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed polynucleotides. Because the claimed

Art Unit: 1642

invention is not supported by a specific asserted utility for the reasons set forth, credibility of any utility cannot be assessed. Thus, applicants arguments have not been found persuasive, and the rejection is maintained.

Claims 35-45 remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 39-41 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record with regards to “encodes an open reading frame of at least 5 amino acids” and “encoding at least one epitope” in Paper No. 16, pages 10-13.

Applicants argue (Paper No. 20, page 9) that the claims have been cancelled and that new claims 35-45 do not contain “percent identify” language. This argument has been considered but it not found persuasive. The written description rejection still applies to the encoding language of epitopes and minimally expressed amino acids for the reasons of record. Thus, applicants arguments have not been found persuasive, and the rejection is maintained.

Art Unit: 1642

NEW OBJECTIONS

Claim 45 is objected to for reciting nucleotides "518-284". For the purposes of this Action it was assumed that Claim 45 was drawn to nucleotides "51-284". Correction or clarification is required.

All other rejections/objections are withdrawn in view of applicants amendments there to.

Conclusion

Applicant's amendment necessitated the new ground(s) of objection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Application/Control Number: 09/092,296
Art Unit: 1642

Page 7


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
October 20, 2001


ART UNIT 1642
SUPERVISORY PATENT EXAMINER
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